NDA 19-653/S-027
NDA 19-697/S-024

R.W. Johnson Pharmaceutical and Research Institute
Attention: William R. Sisco
Associate Director, Regulatory Affairs
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602

JAN 16 2001

Dear Mr. Sisco:

Please refer to your supplemental new drug applications dated July 18, 2000, received July 19, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORTHO-CYCLEN® (norgestimate/ethinyl estradiol) Tablets, ORTHO TRI-CYCLEN® (norgestimate/ethinyl estradiol) Tablets.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the graphics and wording for points 4 and 5 of the "Instructions for using your Diapak® Tablet Dispenser" section of the Detailed Patient Labeling/Brief Summary Patient Package Insert, approved on November 22, 1999.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (patient package insert submitted July 18, 2000). Accordingly, these supplemental applications are approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jennifer Mercier, B.S., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Susan Allen, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research